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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,372	07/02/2001	Mark E. Van Dyke	KER020/4-005CON	3035

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,372	VAN DYKE ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-65 and 67-96* is/are pending in the application.

4a) Of the above claim(s) *69-92 and 94-96* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55-65,67,68 and 93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/21/03; 1/8/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' for RCE, amendment and IDS, all filed 07/21/2003; and IDS, filed 01/08/2004.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/21/2003 has been entered.

Election/Restrictions

2. Applicant's election without traverse of species "powder" in the reply filed on 02/28/2002 is acknowledged.

3. Claims 69-92, 94-96 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/28/2002.

Claim 66 has been canceled. Claims 55-65, and 67-96 are pending. Claims 69-92, and 94-96 have been withdrawn from consideration. Claims 55-65, 67, 68 and 93 are included in the prosecution.

Specification

4. The attempt to incorporate subject matter into this application by reference to prior patent applications, 08/979,456, 08/979,526 and 09/198,998, is ineffective because there is an essential material but is found in pending US applications and no statement of being incorporated by reference. The application as filed clearly conveys an intent to incorporate these specific material by reference.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 55-65, 67, 68 and 93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed in the parent application 09/330,550 lacks support to the limitation: "about

90% of said water soluble peptides are between about 300 and about 1300 daltons in molecular weight". Original claims 1-54 in the present application and in the parent application do recite this limitation. The specification only disclosed 850 daltons molecular weight, page 9, line 7.

7. Claims 55-65, 67, 68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for topical composition, does not reasonably provide enablement for any other composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is topical composition comprising soluble peptides of a specific molecular weight. Nowhere in the specification applicants disclosed composition other than topical.

The breadth of the claims: The claims are broad. The claims encompass wide varieties of compositions including oral and parentral.

The state of the prior art: The state of the art recognized peptides administered topically to treat wounds.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The specification provides no guidance, in the way written description, on composition comprising water soluble peptides that is administered by any route other than topical administration for wound treatment or as an implant. It is not obvious from the disclosure of topical composition comprising peptides if any other composition comprising peptide will work in terms of wound treatment. *In re Dreshfield,* 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The article "Broader than the Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. *See In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of guidance from the specification and from the prior art with regard to composition comprising soluble peptides used for treating wound or implantation that is administered by any other route than topically makes practicing the claimed invention unpredictable in the terms of other forms of the composition.

The presence or absence of working examples: The specification discloses topical composition for treating wounds. No working examples to show other compositions such as oral or parentral. Therefore, the specification has enabled only topical composition.

The quantity of experimentation necessary: The practitioner would turn to trial and error experimentation to practice the instant composition for treating wound or for implantation using non-topical composition without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 55-65, 67, 68 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,495,173 ('173).

US '173 teaches composition comprising keratin and method for its production. The process included the steps of oxidizing animal or human hair, feathers, claws, horns, hoofs, scales and the like. Oxidizing agents included peroxides or peracetic acid. The oxidation is followed by neutralization then gel filtration. The filtrate is dried, i.e. form powder. Solvent used to solubilize keratin is ethanol or methanol. The product produced by the method of the reference could have molecular weight of 200-5000. See col.2, lines 13-15, 21-24, 31-42; col.4, lines 52-55; col.5, lines 1-3, 45-50, 53-54; col.10, lines 15-17. Keratin is made of peptides. The process of production does not impart patentability to product claims.

However, US '173 does not teach the amount of peptides having the low molecular weight of 200-5000.

The amount of the peptides does not impart patentability to composition claims since it has been held that where the general conditions of a claim are disclosed in the

prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

11. Claims 55-65, 67, 68 and 93 rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,276,138 ('138) in view of US 6,506,732 ('732).

US '138 teaches a solubilized keratin powder from animal hair or wool (abstract; col.65-67). The method of production included the steps of oxidation by hydrogen peroxide or peracetic acid; precipitation of a powder; and using solvent such as acetone, methanol or ethanol (col.3, lines 3-5, 21-24; col.4, lines 3, 20-28). Keratin is made of peptides. The process of production does not impart patentability to product claims.

However, US '138 does not teach the low molecular weight of the peptide or its amount in the composition.

The claimed molecular weights do not impart patentability to the claims, absent evidence to the contrary.

The amount of the peptides does not impart patentability to composition claims since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

US '732 teaches topical composition that exhibits wound healing and cell growth properties but does not have allergic activities, said composition comprising soluble peptides having molecular weight between 200-1400 (abstract; col.2, lines 31-50).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising soluble peptides as disclosed by US '138, and select peptides having low molecular weight in the range of 400-1400 daltons as disclosed by US '732, motivated by the teaching of US '732 that the low molecular weight peptides are suitable for topical composition that exhibits wound healing and cell growth properties but does not have allergic activities, with reasonable expectation of having topical composition comprising low molecular weight peptides that is useful for wound healing and cell growth promotion with minimum allergic activities.

12. Claims 55-65, 67, 68 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,763,583 ('583) in view of US '732.

US '583 teaches a water soluble protein derived from human or animal hair (abstract; col.2, lines 15-18, 57-62; col.4, lines 49-50). The soluble protein is useful in cosmetics and medicines (col.6, lines 20-24). The soluble protein is produced by the process that comprised the steps of oxidation using hydrogen peroxide, neutralization of the produced aqueous solution followed by filtration (col.3, lines 20-25; col.4, lines 1-3, 14-23). Organic solvents are used such as methanol and ethanol (col.5, lines 66-67; col.6, lines 15-17). The process of production does not impart patentability to product claims.

However, US '583 does not teach the low molecular weight of the peptide or its amount in the composition.

The claimed molecular weights do not impart patentability to the claims, absent evidence to the contrary.

The amount of the peptides does not impart patentability to composition claims since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

US '732 teaches topical composition that exhibits wound healing and cell growth properties but does not have allergic activities, said composition comprising soluble peptides having molecular weight between 200-1400 (abstract; col.2, lines 31-50).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising soluble peptides as disclosed by US '583, and select peptides having low molecular weight in the range of 400-1400 daltons as disclosed by US '732, motivated by the teaching of US '732 that the low molecular weight peptides are suitable for topical composition that exhibits wound healing and cell growth properties but does not have allergic activities, with reasonable expectation of having topical composition comprising low molecular weight peptides that is useful for wound healing and cell growth promotion with minimum allergic activities.

13. Claims 55-56, 67, 68 an d93 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,932,552 ('552) in view of US '732.

US '552 teaches keratin composition for wound dressing and scaffolding (abstract; col.2, lines 45-51; col.3, lines 19-25; col.5, lines 1-7). Keratin is derived from human or animal hair (col.2, lines 52-54). The keratin is formed by a process comprising the steps of oxidation using peracetic acid, filtration, drying, forming a powder (col.2, lines 57-64; col.3, lines 40-65). The process also included the step of neutralization by a base (col.2, lines 67-col.3, line 3). The process of production does not impart patentability to product claims.

However, US '552 does not teach the low molecular weight of the peptide or its amount in the composition.

The claimed molecular weights do not impart patentability to the claims, absent evidence to the contrary.

The amount of the peptides does not impart patentability to composition claims since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

US '732 teaches topical composition that exhibits wound healing and cell growth properties but does not have allergic activities, said composition comprising soluble peptides having molecular weight between 200-1400 (abstract; col.2, lines 31-50).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising soluble peptides as disclosed by US '552, and select peptides having low molecular weight in the range of 400-1400 daltons as disclosed by US '732, motivated by the teaching of US '732 that

the low molecular weight peptides are suitable for topical composition that exhibits wound healing and cell growth properties but does not have allergic activities, with reasonable expectation of having topical composition comprising low molecular weight peptides that is useful for wound healing and cell growth promotion with minimum allergic activities.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,877,227 disclosed composition for topical use comprising peptides having low molecular weight, as low as 200.

Response to Arguments

15. Applicant's arguments with respect to claims 55-96 have been considered but are moot in view of the new ground(s) of rejection.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

Isis Ghali